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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|-------------------------------------------------------------|-------------------------------|----------------------|---------------------|------------------|
| 10/645,915 | 08/21/2003 | Christopher Marrs | NEU-5006 | 9584 |
| 27777 PHILIP S. JOH | 7590 04/04/200 NSON | EXAMINER | | |
| JOHNSON & J | OHNSON | VAKILI, ZOHREH | | |
| ONE JOHNSON & JOHNSON PLAZA NEW BRUNSWICK, NJ 08933-7003 | | | ART UNIT | PAPER NUMBER |
| | | | 1614 | |
| | | | | |
| | | | MAIL DATE | DELIVERY MODE |
| | | | 04/04/2008 | PAPER |

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

| Office Action Communication | | Application | n No. | Applicant(s) | | | | |
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| | | 10/645,91 | 5 | MARRS, CHRISTOPHER | | | | |
| | Office Action Summary | Examiner | | Art Unit | | | | |
| | | ZOHREH | VAKILI | 1614 | | | | |
| Period fo | The MAILING DATE of this communication or Reply | appears on the | cover sheet with the c | orrespondence a | ddress | | | |
| WHIC - Exter after - If NC - Failu Any | ORTENED STATUTORY PERIOD FOR RECHEVER IS LONGER, FROM THE MAILING asions of time may be available under the provisions of 37 CFI SIX (6) MONTHS from the mailing date of this communication period for reply is specified above, the maximum statutory per to reply within the set or extended period for reply will, by streply received by the Office later than three months after the med patent term adjustment. See 37 CFR 1.704(b). | G DATE OF TH R 1.136(a). In no even n. eriod will apply and wi tatute, cause the appl | IS COMMUNICATION int, however, may a reply be tind the spire SIX (6) MONTHS from the ication to become ABANDONE | N. nely filed the mailing date of this of U.S.C. § 133). | | | | |
| Status | | | | | | | | |
| 1) 又 | Responsive to communication(s) filed on 1 | 4 June 2007 | | | | | | |
| • | Responsive to communication(s) filed on <u>14 June 2007</u> . This action is FINAL . 2b) This action is non-final. | | | | | | | |
| 3) | , _ | | | | | | | |
| ٥,١ | closed in accordance with the practice under <i>Ex parte Quayle</i> , 1935 C.D. 11, 453 O.G. 213. | | | | | | | |
| Dispositi | on of Claims | | | | | | | |
| · · · | Claim(s) <u>1-20</u> is/are pending in the applicat | tion | | | | | | |
| - | 4a) Of the above claim(s) <u>2-5,7,12-15 and 18</u> is/are withdrawn from consideration. | | | | | | | |
| | (a) Of the above claim(s) <u>2-3,7,72-73 and 78</u> is/are withdrawn from consideration. Claim(s) is/are allowed. | | | | | | | |
| · — | 6)⊠ Claim(s) <u>1,6,8-11,16,17,19 and 20</u> is/are rejected. | | | | | | | |
| 7) | Claim(s) is/are objected to. | ojootoa. | | | | | | |
| · — | Claim(s) are subject to restriction ar | nd/or election re | equirement. | | | | | |
| | on Papers | | | | | | | |
| | | • | | | | | | |
| • | The specification is objected to by the Exan | | | | | | | |
| 10) | The drawing(s) filed on is/are: a) | | - | | | | | |
| | Applicant may not request that any objection to | | | | | | | |
| Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d). | | | | | | | | |
| 11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152. | | | | | | | | |
| Priority ι | ınder 35 U.S.C. § 119 | | | | | | | |
| 12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f). a) All b) Some * c) None of: 1. Certified copies of the priority documents have been received. 2. Certified copies of the priority documents have been received in Application No 3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)). * See the attached detailed Office action for a list of the certified copies not received. | | | | | | | | |
| 2) Notice 3) Inform | t(s) e of References Cited (PTO-892) e of Draftsperson's Patent Drawing Review (PTO-948) mation Disclosure Statement(s) (PTO/SB/08) r No(s)/Mail Date |) | 4) Interview Summary Paper No(s)/Mail Da 5) Notice of Informal P 6) Other: | ate | | | | |

DETAILED ACTION

Claims 1-20 are presented for examination.

Applicant's Amendment filed December 14, 2007 has been received and entered into the present application. Accordingly, claims 1-4 and 6 are currently amended. Claims 1, 6, 8-11, 16-17, and 19-20 are pending and are herein examined on the merits.

Applicant's arguments, filed December 14, 2007, have been fully considered. Rejections not reiterated from previous Office Actions are hereby withdrawn. The following rejections are either reiterated or newly applied. They constitute the complete set of rejections presently being applied to the instant application.

Maintained Claim Rejections - 35 USC § 112, First Paragraph

The rejection of claims 11 and 17 under 35 U.S.C. 112, first paragraph as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention, has been maintained for the reasons stated in the prior Office Action, June 14, 2007.

The following is a quotation of the first paragraph of 35 U.S.C. 112:

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The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 11 and 17 remain rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement for the reasons already made of record at pages 2-5 of the previous Office Action dated June 14, 2007.

Applicant traverses the rejection, stating that the derivatives are "specifically "Isoascorbic acid derivative[s] and tocopherol derivative[s]," which are not lacking in chemical structural information, highly variant, nor encompassing a myriad of possibilities. Applicant submits that one of ordinary skill in the art would readily understand the scope of these terms.

Applicant's amendments and remarks have been carefully considered in their entirety, but fail to be persuasive in establishing error in the propriety of the present rejection.

The present rejection was set forth in the absence of any specific definition for the term "derivative" in the present specification. In the absence of such a limiting definition clearly delineating what compounds would be considered derivatives appropriate for use in the presently claimed composition, it remains that the term "derivative" is a relative term that do not properly convey what degree or type of derivation that a given compound may have in relation to the parent compound (i.e., isoascorbic acid) and still be considered a "derivative" as intended by Applicant, nor do they properly convey what degree of similarity to the parent compound (i.e., isoascorbic acid) that will still render the compound sufficiently functionally equivalent. Without any limiting definition, or description

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of physical, structural or functional characteristics that would readily identify a compound as a "derivative", it remains that the skilled artisan would not be reasonably apprised of what compounds would be included or excluded from the present claims. As a result, such a skilled artisan would not be reasonably apprised of the metes and bounds of the subject matter for which Applicant seeks patent protection.

In addition, it is noted that Applicant has stated for the record that since the structure of isoascorbic acid and tocopherol are well-known in the art, the Applicants should not be required to illustrate the structure of isoascorbic acid and tocopherol derivative. Applicant is reminded that it is not required to illustrate the structure of a isoascorbic acid derivative and tocopherol derivative, the phrase "derivative" and "derivative thereof" remain open to subjective interpretation, as explained above the term "derivative" is a relative term that do not properly convey what degree of derivation that a given compound may have in relation to the parent compound. Without any limiting definition that would readily identify a compound as a "derivative", the metes and bounds of the subject matter for which Applicant seeks patent protection is unclear and is not concise. For these reasons, and those already made of record at pages 2-5 of the previous Office Action dated June 14, 2007 the rejection of claims 11 and 17 remain proper and is **maintained**.

Maintained Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for

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all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 1, 6, 8-11, 16-17, and 19-20 remain rejected under 35 U.S.C. 103(a) as being unpatentable over Murad (U.S. Patent No. 6630163 B1) and in view of Yusuf et al. (U.S. Patent No. 5583136) already of record, for the reasons of record set forth at pages 5-7 of the previous Office Action dated June 14, 2007.

Murad teaches some non-enzymatic antioxidants, such as Vitamin E (tocopherol), Vitamin A (beta-carotene), and Vitamin C (ascorbic acid) have each been individually applied to assist the skin in scavenging free radicals and neutralizing the harmful effects of UV light. (see col. 1, lines 44-49). Also, an herbal supplement and nutritional suggestions for the maintenance of the skin are disclosed. The herbal supplement consists of extracts of chaparral, dandelion root, burdock root, licorice root, echinacea, yellow dock root, kelp and cayenne (see col. 5, lines 64-67 & col. 6, lines 1-3). The additional pharmaceutical composition may be a moisturizing agent provided in an amount sufficient to facilitate hydration of the skin. The moisturizer may be a mono- or poly-hydroxy acid, a hydrophobic agent or a hydrophilic agent. The mono- or poly-hydroxy acid may be glycolic acid, lactic acid, citric acid, tannic acid, salicylic acid, or a mixture thereof. The hydrophobic agent may be ceramide,

borage oil, tocopherol linoleate, dimethicone, glycerine, or a mixture thereof (see col. 6, lines 38-50). In a preferred embodiment of the pharmaceutical composition, the fruit extract is present in an amount from about 0.01 to 80 weight percent, preferably from about 0.1 to 20 weight percent, and more preferably from about 0.5 to 10 weight percent. Any fruit extract capable of preventing treating or managing skin disorders and/or skin damage is suitable for use in the dermatological agents and methods of the invention. The fruit extract may be obtained from any part of the plant including, for example, the fruit, the skin or rind of the fruit, the seeds, the bark, the leaves, the roots, or the stem (see col. 8, lines 13-29). Moisturizing agents that are hydrophobic agents include, but are not limited to, ceramide, borage oil (linoleic acid), tocopherol linoleate, dimethicone, glycerine, and mixtures thereof. Hydrophobic agents, when present, are believed to moisturize the skin by inhibiting or preventing the loss of water from the skin. The hydrophobic agent, when present, is typically present in an amount from about 0.01 to 2 weight percent, preferably from about 0.05 to 1.5 weight percent, and more preferably from about 0.1 to 1 weight percent of the composition (see col. 10, lines 28-37).

Yusuf et al. teach skin care compositions comprising a water-in-oil emulsion base containing retinoids and at least one imidazole in a free base form and possessing good physical and chemical stability (see abstract). The water-soluble antioxidants which are useful in the compositions of the present invention include ascorbic acid, sodium sulfite, sodium metabisulfite, sodium bisulfite, sodium thiosulfite, sodium formaldehyde sulfoxylate, isoascorbic acid,

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and mixtures thereof as well as any other known water-soluble antioxidant compatible with the other components of the compositions (see col. 6, lines 18-26). The oil-soluble antioxidants which are useful in the compositions of the present invention include butylated hydroxytoluene (BHT), ascorbyl palmitate, butylated hydroxyanisole (BHA), alpha-tocopherol, and mixtures thereof as well as any other known oil-soluble antioxidant compatible with the other components of the compositions (see col. 6, lines 27-34). The antioxidants should be utilized in a stabilizing effective amount and may range in total from about 0.001 to 5.0% based on the weight of the total composition, preferably from about 0.01 to 1.0%. The amount of antioxidants utilized in the compositions of the present invention is dependent in part on the specific antioxidants selected, the amount of and specific retinoid being protected and the processing conditions (see col. 6, lines 35-42). The retinoid compounds which are useful in the compositions of the present invention consist of Vitamin A alcohol (retinol), Vitamin A aldehyde (retinal) and Vitamin A esters (retinyl acetate and retinyl palmitate). These retinoids are utilized in the compositions of the present invention in a therapeutically effective amount that may range from about 0.001 to 5.0% by weight of the total compositions, preferably from about 0.001 to 1.0% (see col. 6, lines 58-65).

It is obvious to one of ordinary skill in the art to use a combination of the composition taught by Murad with the skin care composition taught by Yusuf et al. Murad teaches the extract of herbs/fruits along with tocopherol in the composition and he also presents the same range of concentration for the plant

extract and tocopherol. Yusuf et al. teach a skin care composition containing retinoids, retinol, isoascorbic acid, and tocopherol with the same claimed concentration range.

It would have been obvious to have combined the teachings of Murad and Yusuf et al. and would have been motivated to combine the references because both references combined teach the claimed invention. One would have been motivated to use these two teachings of both compositions that are directed to skin care and treatment and arrive to the claimed composition.

Thus the claimed invention was within the ordinary skill in the art to make and use at the time the claimed invention was made and as a whole, prima facie obvious.

Applicant's amendments and remarks have been carefully considered in their entirety, but fail to be persuasive in establishing error in the propriety of the present rejection.

Response to Argument

Applicant argues that the Examiner has found one reference that discloses fruit extracts and one reference discloses retinoids. Examiner does not agree with Applicant's arguments Murad teaches a composition that contains vitamin E and extract of chaparral used in a skin care product. Yusuf also teaches a skin care composition comprising of retinol, antioxidant, isoascorbic acid and tocopherol. Every component of the composition is described in Yusuf

with the exception of the chaparral extract. Applicant is reminded that the obviousness rejection is not an anticipation rejection. Murad clearly teaches the use of herbal extract in a skin care composition along with other components that are useful in a skin care product and all of the other claimed components of the composition is disclosed by Yusuf. Applicant is reminded an obvious rejection is not an anticipation rejection. In obviousness rejection a combination of references is used, and the references are relied upon in combination and are not meant to be considered separately as in a vacuum. It is the combination of all of the cited and relied upon references that make up the state of the art with regard to the claimed invention. Applicant's claimed invention fails to patentably distinguish over the state of the art represented by the combination of the cited references. *In re Young*, 403 F.2d 754, 159 USPQ 725(CCPA 1968); *In re Keller* 642 F.2d 413, 208 USPQ 871 (CCPA 1981).

Moreover, it is noted that rejections under 35 U.S.C. 103(a) are based on combinations of references, where the secondary references are cited to reconcile the deficiencies of the primary reference with the knowledge generally available to one ordinary skill in the art to show that the differences between Applicant's invention and the prior art are such that they would have been modifications that were *prima facie* obvious to the skilled artisan. It is noted that the claimed invention is not required to be expressly suggested in its entirety by any one or all of the references cited under 35 U.S.C. 103(a). Rather, the test is what the combined teachings of the references would have suggested to those of ordinary skill in the art. See *In re Keller*, 642 F.2d 413, 208 USPQ 871 (CCPA)

1981). Further Applicant refers to Table 3 of the specification for unexpected result. Applicant is reminded that by adding a known compound that has been useful in a skin care product to a known skin care composition to make a better composition is not an invention. Especially, where all the components and their concentration are taught in the above mentioned references. It is also apparent that the combined composition of chaparral and retinoid will yield the same stable composition of the instant claimed invention.

For these reasons, and those already made of record at pages 5-8 of the previous Office Action dated June 14, 2007 of which such reasons are incorporated herein by reference, rejection of claims 1, 6, 8-11, 16-17, and 19-20 remain proper and is **maintained**.

Conclusion

No claims of the present application are allowed.

Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory

action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Zohreh Vakili whose telephone number is 571-272-3099. The examiner can normally be reached on 8:30-5:00 Mon.-Fri.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ardin Marschel can be reached on 571-272-0718. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Zohreh Vakili

Patent Examiner 1614 /Ardin Marschel/

March 26, 2008

Supervisory Patent Examiner, Art Unit 1614

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